REMARKS

New claims 29 through 32 are presented for the Examiner's consideration.

New claim 29 defines biologically active recombinant DNA-derived factor IX protein which is novel and unobvious over the art of record in this case. The claimed protein is novel over purified human factor IX obtained from blood plasma in that the claim requires that the recombinant factor IX is "free from contamination by poxviruses and by all plasma constituents". It is well known that high molecular proteins are extremely difficult to purify to the extent of removing all contaminated proteins. One cannot be sure that complete purity has been attained by what appears to be a single band on a gel.

In addition to being free of all plasma constituents, the claimed protein is derived from a single human individual. Thus, in addition to having an amino acid sequence of human factor IX protein or of a protein sufficiently similar thereto to make it acceptable for infusion into human patients suffering from factor IX deficiency, being free of contamination by poxviruses by all plasma constituents and having a specific activity as defined in new claim 29, the claimed protein is polymorphism-free (i.e. monomorphic). This feature is discussed, for example at page 10 beginning at line 34 where it is indicated that the starting factor IX is the cDNA clone cVI described by Anson et al (reference AR). According to Anson et al, at page 1059 "Materials and Methods", clone cVI came from

"library I". Library I is of cDNA prepared from mRNA extracted from "human liver" (left hand column, fourth line between the italicized sub-heading). While there is no specific reference to a "human liver" in Anson et al, such language does appear in reference AL (page 24 line 4), which is the assignee's European patent directed to the cloned gene. Both of the references AL and AR can be rationalized in that, in both instances, the cDNA was fractionated on a Sephacryl S 400 column and the first 70% of the peak extracted with 1:4 butanol-chloroform (see page 25 lines 11-16 of AL and page 1059 left hand column of AR, lines 8-12 under the italicized sub-heading).

For further evidence of non-obviousness of the claimed invention, the Examiner's attention is directed to the three executed declarations submitted with the response of December 22, 1988 and to the discussion of those declarations appearing in that response (the content of which is incorporated into the present paper). In this regard also the Examiner's attention is also drawn to the complete record in this case as embodied in the responses of August 7, 1989, January 28, 1991, August 23, 1991 and August 29, 1991.

Early and favorable action on the present application is awaited.

Respectfully submitted,

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